Scientific Abstract

Peripheral arterial disease (PAD) is a serious medical condition causing arterial insufficiency in up to 5% of men and 2.5% of women over 60 years of age. Although discrete arterial lesions may be amenable to vascular surgery or other interventional therapies, over time many patients develop progressive, diffuse disease and experience claudication with limited capacity for exercise. Severe persistent ulcers often develop in the ischemic limb and lead to tissue loss. The primary objective of this Phase I trial is to evaluate the safety and tolerability of VLTS-589 in subjects with PAD. VLTS-589 is a non-viral, plasmid-DNA gene transfer agent that encodes for the Developmentally-regulated Endothelial Locus-1 gene. Del-1 is an angiogenic integrin receptor ligand. In animal models of limb ischemia, Del-1 has been shown to elicit development of new collateral vessels and improve exercise tolerance. VLTS-589 is administered by intramuscular (IM) injection into the diseased limb. Toxicology studies in rabbits indicate that both repeated IM and bolus IV administrations of VLTS-589 are without serious adverse effects.